APR 1 9 2002

K014123

510(k) SUMMARY

SUBMITTED BY: Becton, Dickinson and Company
7 Loveton Circle
Sparks, MD 21152

CONTACT: Jody Hoffmann, Regulatory Affairs Specialist
TELEPHONE: (410) 316-4192

PREPARED: April 12, 2002

DEVICE NAME: BACTEC® MGIT™ 960 SIRE Kits

PREDICATE DEVICES: Method of Proportion agar plates
BACTEC® 460TB SIRE Kit

INTENDED USE: The BACTEC® MGIT™ 960 SIRE Kit is a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to streptomycin (STR), isoniazid (INH), rifampin (RIF) and ethambutol (EMB). The BACTEC® MGIT™ 960 STR 4.0 Kit and the BACTEC® MGIT™ 960 INH 0.4 Kit are for testing at higher drug concentrations.

The BACTEC® MGIT™ 960 SIRE kits are used with the BACTEC® MGIT™ 960 System.

DEVICE DESCRIPTION:

The BACTEC® MGIT™ 960 SIRE susceptibility test kit is used with the BBL® Mycobacteria Growth Indicator Tube (MGIT™)-7mL on the BACTEC® MGIT™ 960 System. The tube is supplemented with BACTEC® MGIT™ 960 SIRE Supplement enrichment and prepared with the appropriate dilutions of streptomycin, isoniazid, rifampin and ethambutol as the mechanism for performing the susceptibility test.

The BACTEC® MGIT™ 960 SIRE test utilizes a four to thirteen day testing protocol. A standardized suspension of *Mycobacterium tuberculosis* growth, from either solid or broth culture media, is prepared. An appropriate dilution is made of this suspension and 0.5 mL is inoculated into a Growth Control tube (drug-free) and tubes containing streptomycin, isoniazid, rifampin and ethambutol (this is referred to as an AST Set). The test interpretation is based on growth of the *Mycobacterium tuberculosis* isolate in the Growth Control tube compared to the growth in the drug-containing tubes.

At the completion of the susceptibility testing protocol, the instrument reports a susceptible or resistant result for each drug at the concentration(s) being tested.

DEVICE COMPARISON:

The BACTEC® MGIT™ 960 SIRE susceptibility test is similar to the Method of Proportion (MOP) susceptibility test method in that:

- Both methods test drug susceptibility of *Mycobacterium tuberculosis* culture isolates.
- Both methods use the same culture source, either liquid or solid culture medium, for preparation of organism inoculum.
- Both methods use the antimycobacterial drug ethambutol.
- Both methods compare organism growth in a control to organism growth in the presence of the drug to obtain the susceptibility result.
- Both methods report test results as susceptible (S) or resistant (R).

The BACTEC® MGIT™ 960 SIRE susceptibility test differs from the MOP susceptibility test method in that:

- The BACTEC® MGIT™ 960 SIRE kits use a modified Middlebrook 7H9 broth as the growth medium while the MOP method uses Middlebrook 7H10 agar as the growth medium.
- The BACTEC® MGIT™ 960 SIRE test utilizes a four to thirteen day testing protocol while the MOP method requires a three week (21 day) testing protocol.
- The BACTEC® MGIT™ 960 SIRE test is automatically monitored by the instrument to detect organism growth using an oxygen sensitive fluorescent sensor while the MOP method requires manual monitoring of the plates to visually detect growth.
- The BACTEC® MGIT™ 960 SIRE test data are automatically interpreted by the instrument software while the MOP susceptibility test data are manually calculated for result interpretation.

The BACTEC® MGIT™ 960 SIRE susceptibility test is similar to the BACTEC® 460TB SIRE susceptibility test method in that:

- Both methods test drug susceptibility of *Mycobacterium tuberculosis* culture isolates.
- Both methods use the same culture source, either liquid or solid culture medium, for preparation of organism inoculum.
- Both methods use modified Middlebrook 7H9 broth as the growth medium.
- Both methods use the antimycobacterial drug ethambutol.
- Both methods compare organism growth in a control to organism growth in the presence of the drug to obtain the susceptibility result.
- Both methods report test results as susceptible (S) or resistant (R).

The BACTEC® MGIT™ 960 SIRE susceptibility test differs from the BACTEC® 460TB SIRE susceptibility test method in that:

- The BACTEC® MGIT™ 960 SIRE test utilizes a four to thirteen day testing protocol while the BACTEC® 460TB SIRE method utilizes a four to twelve day testing protocol.
- The BACTEC® MGIT™ 960 SIRE test is automatically monitored by the instrument to detect organism growth using an oxygen sensitive fluorescent sensor while the BACTEC® 460TB SIRE method requires manual testing of the culture bottles to detect organism growth using a radioactive labeled end product.
- The BACTEC® MGIT™ 960 SIRE test data are automatically interpreted by the instrument software while the BACTEC® 460TB SIRE susceptibility test data are manually calculated for result interpretation.

SUMMARY OF PERFORMANCE DATA:

Analytical studies:

Lot Reproducibility

Reproducibility of the BACTEC® MGIT™ 960 SIRE ethambutol susceptibility test was evaluated using twenty-five *M. tuberculosis* strains (to include five ATCC® strains). Each strain was tested using the BACTEC® MGIT™ 960 ethambutol test at the critical drug concentration. Observed results were compared to the expected results. The overall reproducibility for the BACTEC® MGIT™ 960 ethambutol test at the critical concentration is 100%.

CDC Challenge Panel Testing

The performance of the BACTEC® MGIT™ 960 SIRE ethambutol susceptibility test was evaluated using a panel of thirty challenge strains obtained from the Centers for Disease Control and Prevention (CDC), GA, USA. Observed results were compared to the CDC expected results. The overall agreement of the BACTEC® MGIT™ 960 ethambutol test at the critical concentration with CDC expected results is 100%.

Clinical Evaluation

The BACTEC® MGIT™ 960 SIRE ethambutol susceptibility test was evaluated at four geographically diverse clinical sites composed of regional reference centers and university hospital-based laboratories, including one foreign site.

Reproducibility Testing

The reproducibility of the BACTEC® MGIT™ 960 SIRE ethambutol test was evaluated at the clinical sites using a panel of ten qualified strains. Observed

results were compared to the expected results. Overall reproducibility for the BACTEC® MGIT™ 960 ethambutol test at the critical concentration is 97.5%.

CDC Challenge Panel Testing

The performance of the BACTEC® MGIT™ 960 SIRE ethambutol susceptibility test was evaluated using a panel of thirty challenge strains obtained from the Centers for Disease Control and Prevention (CDC), GA, USA. Observed results were compared to the CDC expected results. The overall agreement of the BACTEC® MGIT™ 960 ethambutol test at the critical concentration with CDC expected results is 93.3%

Clinical Isolate Testing

A total of 106 clinical isolates of *M. tuberculosis* were tested with the BACTEC® MGIT™ 960 SIRE ethambutol susceptibility test and the MOP susceptibility test. This included testing of both fresh clinical and stock isolates from both liquid and solid culture sources. This generated a total of 223 test results for the ethambutol test at the critical concentration.

Category agreement was calculated for isolates from both liquid and solid source cultures tested at EMB 5.0. The agreement for liquid source susceptible strains is 97% and for resistant strains is 85%. The agreement for solid source susceptible strains is 99% and for resistant strains is 80.0%.

All isolates with discordant BACTEC® MGIT™ 960 EMB 5.0 results were tested by MOP at two independent sites. Of the four discordant EMB resistant (R-960, S-MOP) isolates, one had resistant results from both sites and three had susceptible results from both sites. Of the eight discordant EMB susceptible (S-960, R-MOP) isolates, six had susceptible results from both sites and two had resistant results from one site and susceptible results from the other site.

The overall performance data demonstrate that the BACTEC® MGIT™ 960 SIRE ethambutol susceptibility test, used with the BACTEC® MGIT™ 960 System, is substantially equivalent[1] to the Method of Proportion susceptibility test that was in use prior to May 28, 1976.

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[1] The term "substantial equivalence" as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

APR 1 9 2002

Ms. Jody J. Hoffman
Regulatory Affairs Specialist
BD Diagnostic Systems
7 Loveton Circle
Sparks, MD 21152-0999

Re: k014123
Trade/Device Name: BACTEC® MGIT™ 960 SIRE Kits – Ethambutol at 5µg/ml
Regulation Number: 21 CFR 866.1640
Regulation Name: Antimicrobial Susceptibility Test Powder
Regulatory Class: Class II
Product Code: MJA
Dated: March 11, 2002
Received: March 12, 2002

Dear Ms. Hoffman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): _____

Device Name: BACTEC® MGIT™ 960 SIRE Kits

Indications for Use:

The BACTEC® MGIT™ 960 SIRE Kit is a rapid qualitative procedure for susceptibility testing of *Mycobacterium tuberculosis*, from culture, to streptomycin (STR), isoniazid (INH), rifampin (RIF) and ethambutol (EMB). The BACTEC® MGIT™ 960 STR 4.0 Kit and the BACTEC® MGIT™ 960 INH 0.4 Kit are for testing at higher drug concentrations.

The BACTEC® MGIT™ 960 SIRE kits are used with the BACTEC® MGIT™ 960 System. The BACTEC® MGIT™ 960 SIRE Kit final test concentrations are 1.0 µg/mL for streptomycin, 0.1 µg/mL for isoniazid, 1.0 µg/mL for rifampin and 5.0 µg/mL for ethambutol. The BACTEC® MGIT™ 960 STR 4.0 Kit final test concentration is 4.0 µg/mL for streptomycin and the BACTEC® MGIT™ 960 INH 0.4 Kit final test concentration is 0.4 µg/mL for isoniazid.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Freddie T. Poole

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K014123

*Prescription Use Only

(Optional Format 3-10-98)